IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI CENTRAL DIVISION

BECKY J. WRIGHT, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 06-CV-4183-NKL
	)	
AMERICAN HOME PRODUCTS CORPORATION, et al.	)	
	)	
Defendants.	)	

ORDER

This case involves alleged injuries suffered by Plaintiff Becky Wright as a result of ingesting fenfluramine, marketed as Pondimin, by its manufacturer(s) and/or marketer(s): American Home Products Corporation, Wyeth, Inc. and Wyeth-Ayerst International, Inc.[1] Pending before the Court are both parties motions to Exclude or Limit Certain Testimony, [Doc. ## 39, 41, 44, 47, 48, 51, 53, 55 and 57]. For the reasons stated herein, Plaintiff's Motion is DENIED and Defendants' Motions are GRANTED in part and DENIED in part.

I. Background

Plaintiff Becky J. Wright ("Wright") filed this product liability action to recover damages for injuries she allegedly sustained from using fenfluramine ("Pondimin"), a prescription diet drug. Her husband, Ernest, brings suit for loss of consortium as a result

[1] When fenfluramine was prescribed in combination with the drug phentermine, these weight-loss drugs were popularly known, advertised, promoted and referred to as "phen-fen" or "fen/phen."

of Wright's injuries. Wright suffers from a fatal disease called Primary Pulmonary Hypertension ("PPH") for which there is no cure.[2] Wright alleges that her PPH was induced by ingesting Pondimin. Wright's physician, Dr. David Scott, prescribed Pondimin to Wright in April, 1996. Wright alleges the following claims against Wyeth: (1) negligence and negligence per se; (2) design and marketing defect; (3) failure to warn; (4) misrepresentation and fraudulent misrepresentation; (5) strict product liability; and, (6) breach of implied warranty of merchantability. Wright's claims are similar to those asserted in other actions filed by plaintiffs across the country claiming damages allegedly resulting from the manufacture and sale of Pondimin and dexfenfluramine ("Redux") (collectively "the diet drugs").[3] Defendants American Home Products Corporation, Wyeth, Inc., and Wyeth-Ayerst International, Inc. (collectively "Wyeth"), manufactured and distributed the diet drugs. Wyeth withdrew the diet drugs from the world market on September 15, 1997. Because the dispute involves a serious disease for which medical research has not established a firm causative mechanism or process, fact-intensive testimony from Wright's treating physicians and medical experts will play a determinative role in its resolution.

II. Discussion

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[2] The medically accepted nomenclature for Wright's condition has shifted with advances in research and therapy. "Primary Pulmonary Hypertension" originally referred to pulmonary hypertension of unknown cause. The prevalent term is now "idiopathic pulmonary arterial hypertension." (Doc. 82, 8).

[3] Pondimin is Wyeth's trade name for the drug fenfluramine. Redux is Wyeth's trade name for the drug dexfenfluramine.

A party seeking to introduce expert testimony bears the burden of establishing the admissibility of the testimony. *Lauzon v. Senco Products, Inc.*, 270 F.3d 681, 686 (8th Cir. 2001). To be admissible, expert testimony must be both relevant to a material issue and reliable. *Margolies v. McCleary*, Inc., 447 F.3d 1115, 1120 (8th Cir. 2006). Under Federal Rule of Evidence 702, if specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case. Expert testimony may not be permitted where it is based upon speculation. *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1057 (8th Cir. 2000).

A. Evidence Supporting Causation

1. Motions to Exclude or Limit Testimony based on the IPPHS

The International Primary Pulmonary Hypertension Study ("IPPHS") is a seminal study exploring the relationship between diet drugs and PPH. *See Smith v. Wyeth-Ayerst Laboratories Co.*, 278 F. Supp. 2d 684, 689 (W.D.N.C. Apr. 17, 2003). The IPPHS drew conclusions based on 95 PPH cases "along with 335 physician-based control cases from France, United Kingdom, Belgium, the Netherlands, and Switzerland." *Id.* The overall finding of the IPPHS was that "use of appetite-suppressant drugs, regardless of duration

of exposure and/or the onset of symptoms, results in an increased risk (630%) of PPH." *Id*. at 691.

In addition to finding an overall enhanced risk of developing PPH, the authors of the study conducted two "subset analyses": 1) short term users (90 days or less) and long term users (over 90 days); and 2) recent users (demonstrating symptoms within 364 days) and past users (demonstrating symptoms more than one year after use). The "sole purpose" for conducting the subset analyses was to establish causation. *Id*. at n. 21. Long term users have a relative risk of 2,310% while recent users have a relative risk of 1,010%. (Doc. 48, 4).[4] The converse statements are not necessarily true. For example, while the IPPHS may be used in support of the statement that long term users face an enhanced relative risk, it is not more likely true than not that short term users *do not* face an enhanced relative risk. Wright is a short term, recent user. She took Pondimin for no more than eight weeks and demonstrated symptoms within two months. (Doc. 48, 4).

After being diagnosed with PPH, Wright sought treatment from the Mayo Clinic in Rochester, Minnesota where she was treated by Michael McGoon, M.D. In the course of his treatment, McGoon indicated to her that "we could not state with certainty whether anybody's pulmonary hypertension was due to a toxic exposure but could only rely on statistical probabilities." (Doc. 74 Ex. I). McGoon stated that the "statistical probabilities

[4] When there is no known cause, PPH occurs in the general population at the rate of 1 to 2 cases per million annually and women between the ages of 20 and 50 are considered a high risk group for the disease. Smith v. Wyeth, 278 F.Supp. 2d 689 (W.D.N.C. 2003).

for two months (especially one week)[5] are quite low as we understand it." *Id*. McGoon then provided Wright examples of how the probabilities played out for a three-month fen-phen user with no diagnosis of pulmonary hypertension (50 chances in a million) and a three-month fen-phen user with a diagnosis of pulmonary hypertension and no other apparent cause (risk that it was fen-phen related was about 20 times higher than it was simply spontaneous).

At his deposition, McGoon explained these statements stating that the IPPHS provides "no evidence that appetite suppressants reduce or increase the risk of patients who have taken the drug for less than three months." (McGoon Dep., 95). He further stated that the IPPHS "only showed definitive odds ratio increased for greater than three months." *Id*. at 127-28. McGoon next stated that "the answer is no" to Wright having a six times greater probability that she got her PPH from "[fen-phen] as opposed to being spontaneous or idiopathic or sporadic." *Id*. at 65-66. McGoon makes no claim to be an epidemiologist or statistician and makes clear that his reading of the IPPHS study is an opinion developed through his treatment of patients. *Id*. at 62.

Wyeth is entitled to argue, based on a treating physician's impression of the IPPHS, that there is no association between diet drug use and PPH for short-term users. Alternatively, Wright is entitled to show that McGoon is simply wrong on the numbers or developed a faulty idea of what the IPPHS data actually told practitioners about the relationship between diet drugs and PPH. A plain reading of the IPPHS provides support

[5]There are disputed facts about whether Wright took the drug for one week or two months.

for Wright's position that there is a linear relationship between diet drug use and risk of developing PPH. (Doc. 74 Ex. B, 613) ("The risk of primary pulmonary hypertension seems to increase steadily with the quantity of appetite suppressants used . . ."). Depending on the conduct of the parties and the evidence produced at trial, Wright may be entitled to certain instructions to the jury regarding the IPPHS, but the record is insufficiently developed to make that determination now.

Similarly, McGoon's statements as to other factors that may have contributed to Wright's PPH were made in the course of his treatment and sufficiently reliable to be admitted. McGoon's statements are appropriately introduced into evidence.

Wyeth's motion to preclude Wright's expert witnesses from testifying that her Pondimin use proximately caused her PPH is equally unavailing. The IPPHS is clearly a central document, the protocols, methodology and findings of which the parties are able to flesh out in front of a jury. It may be true, as Wyeth asserts, that permitting plaintiffs to rely upon an odds ratio of 2.1 would permit them to meet their burden of proof 100% of the time even if "there could only be causation in a maximum of 52% of cases." (Doc. 86, 3). However, it is the role of the jury, not the Court, to determine if Wright's case is within the 52%, or more, of "causation" cases and Wright is entitled to inform the jury, through expert testimony and otherwise, that the IPPHS did not effectively assess the risk for short-term users or that there are important misunderstandings in the lay and expert communities about what the IPPHS actually tells doctors and patients. Moreover, Wright

has set forth substantial evidence from which a reasonable juror could conclude that Wright's short term use of Pondimin proximately caused her PPH.[6]

2. James F. Tritz, M.D. and Stanley R. Horner, M.D.

Wyeth argues that two of Wright's treating physicians, James F. Tritz, M.D. ("Tritz") and Stanley R. Horner, M.D. ("Horner") should be precluded from testifying that diet drugs caused Wright's PPH because they did not opine on causation during the time they treated her nor are they experts concerning the "proper diagnosis, causes, treatments, or prognosis" for PPH. (Doc. 53).[7] Wyeth does not dispute that Tritz and Horner should be able to testify as fact witnesses as Wright's medical providers. Tritz is an "interventionist cardiologist" in Jefferson City, Missouri. Tritz treated Wright between 2001 and 2002 and correctly diagnosed her with PPH. (Doc. 67 Ex. 6). Tritz testified that he would "look for a certain set of causes" of pulmonary hypertension and then refer patients to specialists for causes outside of "thromboembolic disease, congenital heart disease and . . . rheumatic disease that's associated with pulmonary hypertension." (Tritz Dep., 28). Wyeth argues that Tritz "did not know" that diet drugs could cause PPH, although the deposition testimony cited suggests only that Tritz did not know that Wright was taking diet drugs. (Tritz Dep. 112-13) ("At that point in time I did not know – in fact, I did not know that she had used [appetite suppressants]."). Tritz also

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[6] *See e.g.* Eugene Mark, *Fatal Pulmonary Hypertension Associated with Short-Term Use of Fenfluramine and Phentermine*, New Eng. J. Med., 337:9; 602-606 (1997) (describing death of 29-year-old woman after 23 days' use of Pondimin).

[7] The Court finds Wyeth's accusations as to Tritz's "lack of treatment" of Wright unnecessary and totally improper. (Doc. 54, 2).

admitted that he is "not a statistician" and that he did not know what an "absolute risk" was as it relates to the IPPHS and epidemiology. (Tritz Dep., 160, 177).

Horner is an immunologist who practices in Jefferson City, Missouri. Horner has diagnosed 20 to 25 patients with pulmonary hypertension over 20 years. As with Tritz, Horner does not claim to be a statistician, but is knowledgeable about pulmonary hypertension in that frequent causes of the disease are autoimmune in nature. Wright also states that she returned to Horner in 2007, so that his opinion can credibly be stated to be within the course of treatment.

In short, Wyeth's criticisms of Tritz and Horner mirror Wright's criticisms of McGoon. Even if Tritz and Horner reviewed the IPPHS after their treatment of Wright was over (although Horner's has evidently resumed), that does not make their testimony unreliable. *See Nelson v. Am. Home Products Corp*. 92 F. Supp. 2d 954, 968 (W.D. Mo. 2000). Tritz and Horner diagnosed Wright with PPH after other physicians had suspected asthma and the record before the Court does not support Wyeth's contention that these conclusions as to causation were developed only within the context of litigation. Wyeth will be able to explore any weaknesses in Tritz's or Horner's credentials or report during cross-examination. Wyeth's argument clearly goes to weight and not admissibility. To the extent Tritz's and Horner's testimony may be duplicative of other testimony, the Court will address that objection at trial.

3. E. David Scott, M.D.

Wright's physician, David Scott, M.D. ("Scott") prescribed Pondimin to Wright in April, 1996. Scott concludes that had he known about "either the risks of valvular heart disease or all of the reported cases of pulmonary hypertension . . . that Wyeth was aware of, I would have concluded that the risks of Pondimin outweighed any possible benefit to Becky Wright and I would not have prescribed Pondimin to her." (Scott Aff. ¶ 8). Wyeth's motion seeks to preclude Scott from testifying to his "opinion to a reasonable degree of medical certainty as to whether Pondimin could have been, and was, the cause of Plaintiff's PAH." Wright agrees that Scott will not offer such an opinion at trial. Wright does not contend that Scott is an expert on PPH, its diagnosis or treatment, however, Wright preserves her ability to call Scott to the stand to testify that, had he known about risks Wyeth allegedly withheld, he would not have prescribed Pondimin to her.

4. Cheryl Blume, Ph.D.

Wyeth next argues that pharmacologist Cheryl Blume, Ph.D. ("Blume") should be precluded from testifying about the relative risks and benefits of Pondimin or Wyeth's knowledge and intent in marketing Pondimin. Blume has degrees in biology and medical pharmacology and has worked for 30 years in the field of approval and labeling of prescription drugs, including work for the FDA. Blume's expertise extends to analyzing risks and benefits of prescription medications for specific classes of patients before they reach market. (Doc. 68, 6). Blume is clearly qualified to testify about the risks and benefits of Pondimin as it relates to general industry practice and she is qualified as to any

general industry standards Wyeth followed or failed to follow prior to marketing and distributing Pondimin. *Pierce v. Platte-Clay Electric Cooperative, Inc.*, 769 S.W.2d 769, 772 (Mo. 1989) ("Evidence of industry standards is generally admissible as proof of whether or not a duty of care was breached."). Blume will not be permitted to testify as to Wyeth's intent in failing to abide by industry standards, unless she has specific knowledge related to Wyeth's specific intent. The parameters of this limitation must be addressed at trial.

5. Lemuel A. Moye, Ph.D., M.D.

As with Blume, Wyeth argues that Lemuel A. Moye, Ph.D., M.D. ("Moye"), a biostatician, may not testify as to Wyeth's compliance with FDA regulations, risks and benefits of diet drugs, and Wyeth's knowledge and intent regarding its conduct with respect to developing, marketing and distributing Pondimin. Moye is a professor of biostatistics at the University of Texas School of Public Health and has served on an FDA advisory panel for four years, also serving as a clinical trial consultant. There is no serious question as to Moye's credentials and capability to assist the jury in understanding how the FDA reporting and labeling process works and whether or not Wyeth followed that process with respect to Pondimin. *See Smith v. American Home Products Corp*. 278 F. Supp. 2d. 684, 700-01 (W. D. N. C. 2003) ("Given Dr. Moyé's educational background, as well as his experience as a clinical trial investigator and consultant, his qualifications in this area are beyond question. Dr. Moyé can

provide testimony that will be helpful to the jury."). As with Blume, Moye will not be permitted to offer testimony as to Wyeth's specific "intent" unless he has personal knowledge of such intent. Again, the parameters of this limitation must be addressed at trial.

B. Testimony Supporting Damages

1. Lori Hinton, DrPH

Lori Hinton, DrPH, ("Hinton") is a life care planner who has outlined three alternative expense scenarios for Wright, depending on which course of treatment is possible. A Life Care Plan provides a "plan for current and future needs with associated costs, for individuals who have experienced catastrophic injury or have chronic health care needs." (Life Care Plan for Becky Wright, Definition). Wyeth does not dispute Hinton's qualifications or credentials, but instead argues that because she cannot state with any certainty which course of treatment, if any, will be pursued, her testimony would be speculative and therefore inadmissible. In support of its motion, Wyeth cites *Nelson v. American Home Products Corp.*, 92 F. Supp. 2d 954, 967 (W.D. Mo. 2000) and *Pillow v. General Motors Corp.*, 184 F.R.D. 304 (E.D. Mo. 1998), both of which certainly stand for the proposition that an expert's opinions must be based on a reliable methodology. Neither case addressed the situation here: whether Wright's life care plan is so speculative as to warrant exclusion.

However, a number of courts have addressed Wyeth's argument and have permitted damages based on life care plans as long as they are supported by medical

evidence. *See Ballance v. Wal-Mart Stores, Inc.*, 1999 U.S. App. LEXIS 7663 (4th Cir. 1999) ("Nor did the court err in admitting Dr. Sciara's life care plan testimony. Again, Wal-Mart's claim is that because the life care plans are contingent upon future events and choices (i.e. whether Ballance has surgery and whether it is successful), they are speculative and unreliable. But Wal-Mart's objections simply do not implicate the "reliability" of the opinions of either of the Ballances' medical experts. Those experts testified to the eventual consequences of the disease, the treatment options available to Ballance, the likelihood of success of these options, and the cost of care depending on which option Ballance chooses. Wal-Mart was able to cross-examine the Ballances' experts and put on its own expert to refute their testimony."); *Davidson v. United States HHS*, 2007 U.S. Dist. LEXIS 81461 (E.D. Ky. Nov. 2, 2007) (rejecting life care plan because it was based on an institute's programs and services rather than medical evidence). This is also the applicable law in Missouri. *See Mitchum v. Gabbert*, 31 S.W.3d 538, 543 (Mo. Ct. App. 2000). Wyeth offers no serious criticisms of the medical evidence, supplied by Wright's treating physician, Shelly Shapiro, M.D.[8]

2. Everett Dillman, Ph.D.

Wyeth next seeks to exclude testimony from Everett Dillman, Ph.D., ("Dillman") an economist who will testify as to Wyeth's financial worth, because he does not purport

[8] Wyeth provides an exchange taken from Shapiro's deposition in which she said it was "possible" that "as time goes on, more and more treatments will come out that might sustain – that might give people better prognosis transplant-free?" Wyeth's question itself is pure conjecture on treatments that do not currently exist and for which Shapiro could not responsibly speculate. (Shapiro Dep., 154).

to offer evidence as to Wyeth's complete indifference to or conscious disregard for the safety of others - the standards for awarding punitive damages under Missouri law. *Lopez v. Three Rivers Elec. Coop.*, 26 S.W.3d 151, 160 (Mo. 2000) (citation omitted). Dillman will only offer evidence as to Wyeth's ability to pay an award of punitive damages. Alternatively Wyeth argues that Dillman's testimony is unreliable and/or prejudicial.

As a threshold matter, where a plaintiff establishes a submissible case for punitive damages, evidence of the defendant's financial worth is independently relevant and admissible under Missouri law. *Green v. Miller*, 851 S.W.2d 553, 555 (Mo. Ct. App. 1993); *Barnett v. La Societe Anonyme Turbomeca France*, 963 S.W.2d 639, 655 (Mo. Ct. App. 1997). While the U.S. Supreme Court did enumerate factors to be considered in reviewing the *size* of a punitive damages award, the Supreme Court has issued no comment on the propriety of considering a defendant's ability to pay. *See TXO Prod. Corp. v. Alliance Resources Corp.*, 509 U.S. 443, 462 (1993). This is likely true because ability to pay is relevant for purposes of effectively punishing unlawful conduct. The only explicit prohibitions on an award of punitive damages are 1) punishing a defendant for harm caused to non-parties and, 2) depriving a defendant of Due Process protections. *Philip Morris USA v. Williams*, 127 S. Ct. 1057, 1063 (2007). Otherwise, the U.S. Supreme Court has confirmed that punitive damages may properly be imposed to further a State's legitimate interests in punishing unlawful conduct and deterring its repetition. *BMW of N. Am. v. Gore*, 517 U.S. 559, 568 (1996) (citing *Gertz* v. *Robert Welch, Inc.*, 418 U.S. 323, 350, 41 L. Ed. 2d 789, 94 S. Ct. 2997 (1974)).

Dillman will also be permitted to compare the relative financial impact of various punitive damage awards on a typical household and on Wyeth. The purpose of Dillman's comparison is to help the jury understand the punitive effect of an award. *See Zarcone v. Perry*, 572 F.2d 52, 56 (2d Cir. 1978) ("It is true that without . . . evidence [of defendant's net worth] no one can be sure of the severity of the monetary sanction that the jury imposed. A $ 60,000 award may bankrupt one person and be a minor annoyance to another."). An award of punitive damages, if any, will remain subject to statutory and Due Process limits and thus Wyeth will suffer no prejudice, as it asserts.

V. Conclusion

Accordingly, it is hereby

ORDERED that

Wright's Motion to Exclude or Limit Expert Testimony [Doc. #48] is DENIED;

Wyeth's Motion to Exclude the Testimony of Dr. Everett Dillman [Doc. #39] is DENIED;

Wyeth's Motion to Exclude the Testimony of Dr. Lori Hinton [Doc. #41] is DENIED;

Wyeth's Motion to Preclude Dr. Lemuel Moye from Offering Opinion Testimony Concerning Matters Beyond the Scope of his Qualifications [Doc. # 44] is GRANTED as to Wyeth's specific intent and DENIED in all other respects;

Wyeth's Motion to Preclude Dr. Cheryl Blume from Offering Opinion Testimony Concerning Risks and Benefits of Pondimin, the Relationship of Pondimin to PPH and

Wyeth's intent [Doc. #47] is GRANTED as to Wyeth's specific intent and DENIED in all other respects;

Wyeth's Motion to Preclude Dr. Horner from Offering Opinion Testimony Concerning Primary Pulmonary Hypertension [Doc. # 51] is DENIED;

Wyeth's Motion to Preclude Dr. Tritz from Offering Opinion Testimony Concerning Primary Pulmonary Hypertension [Doc. # 53] is DENIED;

Wyeth's Motion to Preclude Dr. Scott from Offering Opinion Testimony Concerning Primary Pulmonary Hypertension [Doc. # 55] is DENIED as moot;

Wyeth's Motion to Preclude Plaintiffs' Experts from Testifying that Plaintiff's Short Term Use of Pondimin was the Proximate Cause for her Pulmonary Hypertension [Doc. #57] is DENIED.

s/ NANETTE K. LAUGHREY
NANETTE K. LAUGHREY
United States District Judge

Dated: April 18, 2008
Jefferson City, Missouri